GE Healthcare

GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116
U.S.A.

Certified Mail Return Receipt Requested

IMPORTANT- ELECTRONIC PRODUCT RADIATION WARNING

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT SYSTEM (S) OF THESE ISSUES AND HOW TO ADDRESS THEM

October 17, 2007

To: **Hospital Administrator**

Director/Manager of Radiology

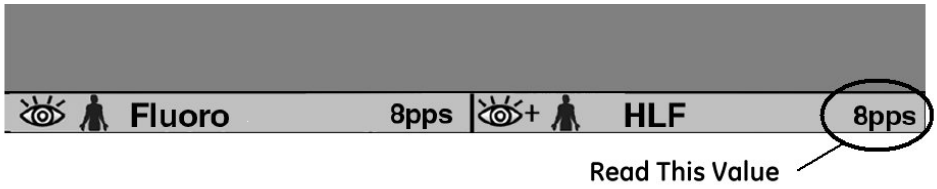
Affected Product: **OEC® 9800 & OEC® 9900 Elite**

In a previous communication GE Healthcare informed customers that some 9800 and 9900 C-Arms might exceed the 20 R/minute limit required by the 21 CFR 1020.32 (d)(2)(iii)(C) when in High Level Fluoro (HLF) Pulsed Mode. This communication is intended to clarify the issue for our users.

The issue described above could occur if the Default Pulse Rate is set to 25 or 30 Pulses Per Second (PPS) on the 9800 or the 9900 C-Arm Workstation. Assemblers, installers, or service personnel can manually change this value using RUS (Remote Utility Suite Software) or RUT (Remote Utility Tool). The user cannot select it.

Please do the following to determine if this issue affects your system:

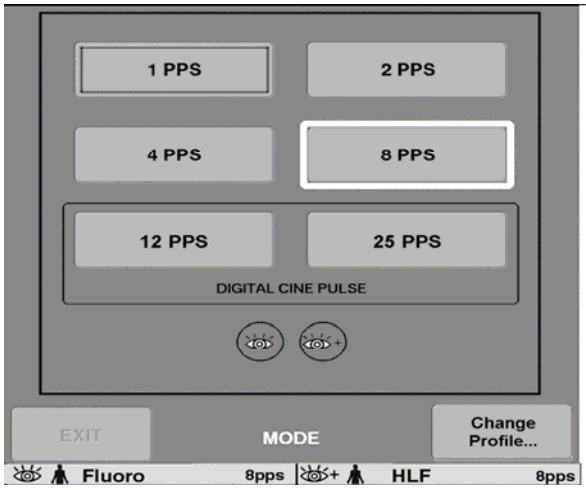
1. Power the system up
2. Press the PULSE button on the C-Arm
3. If 25 or 30 PPS is displayed in the status bar on the right workstation monitor, the Default Pulse Rate is set to 25 or 30 PPS



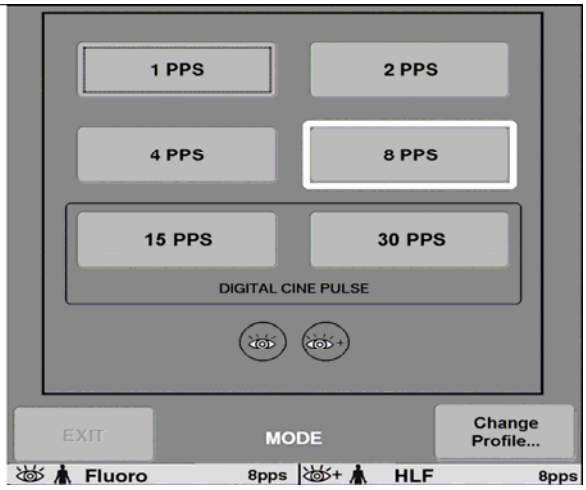
4. **IF 25 OR 30 PPS IS DISPLAYED PLEASE USE THE INTERIM SOLUTION DESCRIBED BELOW**
5. **If 25 or 30 PPS is NOT displayed, your system complies with the Code of Federal Regulations, and no further action is indicated.**
6. **Test is complete. Shut down the system.**

Interim Solution:

Restart the system. Each time the system is used and if Pulsed Fluoro is required, for safe and compliant operation of the system you must select Pulsed Mode from the C-arm Workstation only. Then select the desired pulse rate from the Workstation touch screen. Do not select pulsed mode from the C-arm control panel. . Using this method will prevent the system from operating at 25/30 PPS in the HLF mode. .



Workstation Mode Screen for 50 Hz System



Workstation Mode Screen for 60 Hz System

Also, please be aware that GE Healthcare will execute an inspection (and correction if necessary) of all potentially affected 9800 and 9900 C-Arms. A GE Healthcare Field Service Engineer (or representative) will contact your firm in order to coordinate this activity at no charge.

If you have any questions or concerns regarding these issues, please do not hesitate to contact GE Healthcare Customer Service. For US Customers please contact GE Healthcare Customer Service at 1-800-874-7378 or 1-801-536-4688 as we are available 24/7.

We apologize for any inconvenience and thank you for your attention.

Pete McCabe

Pete McCabe
President and CEO
GE Healthcare, Surgery

Maria Frame

Maria Frame
Vice President of Quality and Regulatory Affairs
GE Healthcare, Surgery